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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/650,274	08/28/2003	Matthew Glenn	13353.1073	7195
20601	7590	01/26/2006	EXAMINER	
SPECKMAN LAW GROUP PLLC 1201 THIRD AVENUE, SUITE 330 SEATTLE, WA 98101			WALICKA, MALGORZATA A	
			ART UNIT	PAPER NUMBER
			1652	
DATE MAILED: 01/26/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/650,274

Applicant(s)

GLENN ET AL.

Examiner

Malgorzata A. Walicka

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 December 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 7-15, 18-23 and 25-33 is/are pending in the application.
- 4a) Of the above claim(s) 1-4, 17, 20, 25 and 26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18, 21-23 and 27-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>Dec 16, 2004</u> . | 6) <input type="checkbox"/> Other: _____ |

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The Response to Restriction Requirement and Preliminary Amendment filed Dec. 20, 2005 is acknowledged. Claims 5-6, 16-17, 19, 24 and 24 have been canceled. Claims 18, 21, 22-26 have been amended. New claims 27-33, which read on the elected invention, have been added. Claims 1-4, 7-15, 18-23 and 25-33 are pending. Claims 18, 21-23 and 27-33 directed to an isolated polypeptide of SEQ ID NO: 172 and its compositions are under examination. Claims 1-4, 7-15, 20, 25-26 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

DETAIL ACTION

1. Restriction/election

Applicant's election, without traverse, of the invention encompassed by Group III directed to polypeptide of SEQ ID NO: 172, encoded by the polynucleotide of SEQ ID NO:73 is acknowledged.

Applicants' reserved their right to rejoin method of claims 25 and 26 once the composition claims are determined to be allowable. Pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86), if product claims are allowable claims 25 and 26 are directed to the process of using the patentable product will be rejoined and fully examined for patentability under 37 CFR 1.104.

2. Priority

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The priority of the claims under examination to the provisional application 60/406,810 filed August 28, 2002 is granted.

3. Objections

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors in the specification of which applicant may become aware.

Claims 23, and 27-33 contain unnecessary colon after "consisting of".

4. Rejections

4.1. 35 USC section 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 18, 21-23 and 27-33 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility.

Applicants assert the polypeptide of SEQ ID NO: 172 is encoded by a gene that is a "Homolog of poxB, encoding a pyruvate oxidase", Table 1, page 71, without presenting the homology percentage or any sequence alignment. Thus, based on the characteristics of having sequence homology to a pyruvate oxidase as evidenced by an

undisclosed sequence analysis, it appears that applicants conclude that the polypeptide of SEQ ID NO: 172 has a function of pyruvate oxidase. It is known in the art that sequence analyses for the purposes of assigning a function to an encoded polypeptide, i.e., sequence annotation, are not sufficient to define the function of a given polypeptide. For example, Brenner (*Trends in Genomics* 15:132-133) teaches that without laboratory experiments to verify the computational methods and their expert analysis, it is impossible to know an encoded polypeptide's function (page 132, top right). As a specific example where sequence analysis would potentially incorrectly assign function, Seffernick et al. (*J Bacteriol* 183:2405-2410) teach two polypeptides encoded by polynucleotides with greater than 99 % identity (page 2407) with distinct functions (page 2405). Therefore, without empirically determining the function of the polypeptide of Seffernick et al., one of ordinary skill in the art may erroneously predict the function based solely on sequence annotation. It is also well known in the art that functional prediction based on sequence analysis frequently results in erroneous functional assignment. Devos et al. (*Trends in Genetics* 17:429-431) teaches that up to 30 % of functional assignments could be in error due to the assumption that similar sequences have similar functions (page 431, left top). Therefore, because applicants have assigned the function of the polypeptide of SEQ ID NO: 172, based on the characteristics as described above, discerned from an undisclosed sequence comparison, additional experimentation would be required to ascertain the function of the polypeptide of SEQ ID NO:172. Applicants themselves do not teach result of any assay, which proved the enzymatic activity of the claimed protein.

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While the assertion of homology is credible the statement of homology does not provide a function for the claimed polypeptide and for that reason utility. The specification must teach a skilled artisan how to use what is claimed not merely provide a blueprint for further experimentation in order for an artisan to identify a use for the claimed invention. In summary, there is no well-established utility for the polypeptide of SEQ ID NO: 172, because its function remains unknown. After further research, a specific and substantial credible utility might be found for the claimed isolated composition. This further characterization, however, is part of the act of invention and until it has been undertaken, Applicant's claimed invention is incomplete. Thus, there has been no immediately apparent or "real world" utility identified as of the filing date of the instant application. Until an actual and specific biologic significance can be attributed to the protein and its gene, one of ordinary skill in the art would be required to perform additional experimentation in order to determine how to use the claimed invention.

Claims 18, 21-23 and 27-33 are also rejected under 35 USC § 112, the first paragraph. Since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention, so that it would operate as intended, without undue experimentation.

In conclusion the claimed polypeptides do not have a real-world use and hence lack utility.

4. 35 USC section 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4.1. Lack of written description

Claims 22 and 27-33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contain subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are directed to:

- 1) a fusion protein comprising SEQ ID NO: 172, or comprising a polypeptide encoded by SEQ ID NO: 73, and
- 2) polypeptides that are at least 75% identical to SEQ ID NO: 172 and possess pyruvate oxidase activity.

Regarding point 1), in the case SEQ ID NO: 172 has pyruvate oxidase the function of the hybrid protein of claim 22 and its composition should be retained. But the claim does not recite it.

Regarding point 2), new claims 28-33 are rejected for new matter which was introduced with the Primary Amendment of Dec. 20, 2005. Neither the specification nor the claims as originally filed state that the polypeptide set forth in SEQ ID NO: 172

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possesses pyruvate oxidase activity. The disclosure states it **is a homolog** of a pyruvate oxidase.

In conclusion, because of lack of description of function of the claimed polypeptides and their compositions, one of skills in the art is not convinced that Applicants were in possession of the claimed invention at the time the application was filed.

4.1.2. Scope of enablement

Even if SEQ ID NO:172 had the function of pyruvate oxidase the following rejection would be proper.

Claims 28-29 and 31-32 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a polypeptide that is set forth by SEQ ID NO: 172 does not reasonably provide enablement for a polypeptide being at least 75% or 90% identical to SEQ ID NO: 172 and retaining the activity of pyruvate oxidase.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims are broader than the enablement provided by the disclosure with regard to the large number of polypeptides that are encompassed by the scope of the claims, as well as polypeptides that are involved.

The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Otherwise, undue experimentation is necessary to make the claimed invention. Factors to be considered in determining whether undue experimentation is required, are summarized *In re Wands* [858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)]. The Wands factors are: (a) the nature of the invention, (b) the breadth of the claim, (c) the state of the prior art, (d) the relative skill of those in the art, (e) the predictability of the art, (f) the presence or absence of working example, (g) the amount of direction or guidance presented, (h) the quantity of experimentation necessary.

The nature and breath of the claimed invention encompasses any polypeptide being at least 75% or 90% identical to SEQ ID NO: 172 and retaining activity of pyruvate oxidase, wherein said polypeptide originates from any natural and man-made source.

While methods of gene cloning and manipulating, testing pyruvate oxidase activity are well known in the relevant art, and skills of the artisans highly developed, to obtain the claimed invention involves experimentation which is not routine. Lack of the lack of teaching the structure/function relationship and lack of instruction as to which amino acids can be changed without losing the required enzymatic activity, imposes on the skilled artisan experimentation that has low probability of success. Providing the structure of SEQ ID NO: 172 is not enabling for modified proteins which are claimed. In conclusion to make and use the claimed invention one having skills in the art is left with experimentation which is undue.

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5. Conclusion


All claims are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Malgorzata A. Walicka whose telephone number is (571) 272-0944. The examiner can normally be reached on Monday-Friday from 10:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Art Unit 1652
Patent Examiner


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